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# Plain Skull Film Radiography in the Management of Head Trauma: An Overview

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BRH
bureau of radiological health

WHO Collaborating Centers for:
- Standardization of Protection Against Nonionizing Radiations
- Training and General Tasks in Radiation Medicine
- Nuclear Medicine

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Bureau of Radiological Health
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## FOREWORD

The Bureau of Radiological Health develops and carries out a national program to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiations and to ensure the safe, efficacious use of such radiations. The Bureau publishes the results of its work in scientific journals and in its own technical reports.

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The Bureau also makes its technical reports available to the World Health Organization. Under a memorandum of agreement between WHO and the Department of Health and Human Services, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

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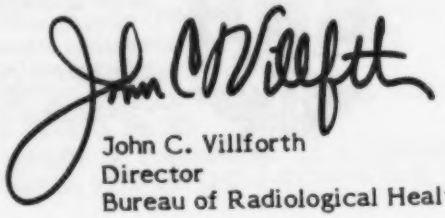

John C. Villforth
Director
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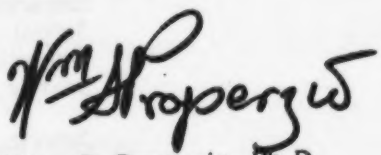
## PREFACE

The purpose of this document is to examine the use of plain skull films in the management of head trauma. The report reviews and examines such issues as utilization, the use of referral criteria, efficacy, economic and social considerations, and radiation risk. The authors identify areas of agreement and disagreement within the medical community, but do not attempt to resolve any controversy.

The Bureau of Radiological Health publishes reports of this nature from time to time to bring together, in one document, issues concerning a particular medical technology which relate to the Bureau's mission and which are being discussed in the literature. The Bureau will use this overview as a resource document for a panel of physicians which will be convened to consider the development of referral criteria for ordering plain film skull radiographs. This report is also likely to be of immediate interest to emergency department physicians and radiologists who are concerned with the appropriate utilization of skull radiography. Those who are interested in exploring the broad societal implications of this health care technology will also find useful information in this overview.

This document also serves to fulfill a request of the National Center for Health Care Technology (NCHCT) for an overview of the use of skull radiography. The NCHCT was established by Congress under Public Law 95-623 (the Health Service Research, Health Statistics, and Health Care Technology Act of 1978), to assess the many complex and interrelated issues which medical technologies pose for the health care professions, for patients and for society. The Center defines health care technology broadly to include any means to prevent, diagnose, or treat disease or promote health. The Center and its advisory body, the National Council on Health Care Technology, expect to use this overview in setting research priorities. The Bureau is pleased to provide this report for their use.



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The opinions and statements contained in this report are those of the author and may not reflect the views of the Department of Health and Human Services (HHS), or necessarily represent the views or the stated policy of the World Health Organization (WHO).

# PLAIN SKULL FILM RADIOGRAPHY IN THE MANAGEMENT OF HEAD TRAUMA: AN OVERVIEW

## INTRODUCTION

The term skull radiography is used to describe the radiographic examination of the cranium and its contents. Although skull radiography is useful to investigate pathological conditions of the skull or brain resulting from disease, it is more frequently used to investigate damage to the skull and/or brain resulting from mechanical force (trauma).

The examination, often called a "skull series," is a set of plain film radiographs made using conventional fixed radiographic equipment. Several views or projections are taken in order to visualize different parts of the skull and brain; no contrast medium is used. A skull series can demonstrate any of the following conditions: chronic raised intracranial pressure (especially in children), abnormal intracranial calcification, shift in the pineal gland (if calcified), abnormalities in relation to the pituitary fossa and internal auditory meatus, local and generalized bone changes, fractures of various types and the presence of foreign bodies (1). Following acute head trauma, skull radiography is employed to detect fractures, pineal shifts or the presence of foreign objects.

Plain skull films do not differentiate among the various blood vessels and tissues in the brain which are similar in density; to visualize these, radiographic studies using a contrast medium are required, e.g., pneumoencephalography, ventriculography and cerebral angiography. Pneumoencephalography and ventriculography are used to visualize the subarachnoid space and the ventricles of the brain, respectively. Cerebral angiography is used to visualize the arterial and venous anatomy of the brain (2).

A series of plain skull films may be taken to evaluate the extent of injury to the skull and cranial contents as a result of trauma, or to investigate suspected non-traumatic pathology of the same region, e.g., recurrent convulsions, epilepsy, tumors or neoplasms.

A skull series is ordered by many physicians for all patients presenting with any history of head trauma. In many instances skull radiographs are ordered routinely to determine if a skull fracture has occurred. This practice continues because some doctors, many lawyers and almost all patients attach high importance to the detection of a skull fracture (3). However, the yield of skull fractures in skull radiography for trauma has been found to range from 2 to 26.6 percent (4-6). The larger values occurred in studies involving only children. In other studies, involving both adults and children, not more than 5 percent of skull x-ray examinations ordered for trauma demonstrated a fracture (7-10). Fractures that were clinically significant, i.e., their identification substantially influenced medical care, ranged only from 0.4 to 2 percent (10).

Although there is some concern that skull films yield little information in the evaluation of seizures and headaches (11,12), there are few articles in the literature that address the overutilization of skull radiography for the investigation of non-traumatic pathological conditions. However, a number of articles have appeared in the literature addressing the overutilization of skull radiography following head trauma. Hence this report will address that issue only.

READEX FICHE

The issue of overutilization of skull radiography will be considered from the following perspectives:

1. the contribution that knowledge of a skull fracture makes to patient care;
2. the efficacy of routine skull radiography;
3. the use of referral criteria to select those patients who are most likely to benefit from skull radiography;
4. the risks associated with the use of skull x-ray referral criteria;
5. alternatives to the use of conventional skull radiography; and
6. the medico-legal issue surrounding skull radiography.

In discussing plain skull films, we will assume that the radiographs have been properly taken, i.e., correct technique factors have been used and the radiographs are diagnostically adequate. This report will not address radiographic quality, repeated radiographs, or questions of a similar nature. Likewise, this report will not address the issue of film interpretation or investigate biases which may exist in the studies quoted.

## BACKGROUND

It is important to diagnose and treat head injuries without delay in order to limit brain damage because damaged neural cells neither repair their injury nor reproduce themselves. Post-trauma patient management should therefore address the reversible sequelae (e.g., cerebral swelling, intracranial bleeding) of the head insult (13). Furthermore, clinical experience indicates that most deaths due to skull trauma and subsequent brain injury occur within 6 hours of the accident (14). Therefore, prompt, effective treatment during that period may be critical.

It is important to immediately identify brain lesions which may require surgery. To accomplish this, physicians may employ angiography, computed tomography (CT) and routine skull exams. In a routine skull series, several different projections may be taken. The number and type of projections depends upon what is suspected; however, a routine skull series normally would include the following projections: lateral, straight posterior-anterior (PA), inclined PA (modified Caldwell projection), anterior-posterior (AP), half-axial (Towne's projection), and an axial (basal) projection (15). These views aid in identifying several types of fractures, a shifted pineal gland (if calcified), any other intracranial calcifications, and foreign bodies, if present (16). Among the medical reasons for detecting a fracture is the assertion that a linear fracture points to the most probable site of intracranial bleeding (16).

Ideally, an attending physician orders skull radiographs after a careful clinical evaluation of the patient. Under those circumstances, a physician can exercise judgment in ordering skull films and need not request the whole series. For example, Bull and Zilkha (17) find little use for performing a complete skull series in patients presenting with no physical signs but who may complain of headache, neck pain, or vertigo. Instead, they suggest that a single lateral skull film be taken to evaluate those problems as well as to check patients with neurological signs. They believe that a single film will suffice for patient screening, and that further exams can be ordered at the radiologist's option. More recently, Masters has also suggested that ordering a complete skull series to rule out significant injury is not justified (18).

In many cases, emergency room personnel may order skull radiographs before a doctor sees the patient, either to save time or as a matter of routine (19,20). Even in those emergency rooms where doctors see patients immediately, the physician may order a skull series

before examining the patient, in order to save time or because the patient's history is not available (20). Even trivial injuries often prompt an order for radiography (19). It has also been alleged that some radiographs are ordered more to satisfy a doctor's curiosity than to assist in a patient's diagnosis (16) and that "it is easier to order an x-ray examination than to think" (21). Overutilization may also be a result of the increase in health insurance coverage. The expense of such examinations is no longer borne by the patient and an important restraining factor is lost (22). In fact, many patients believe their medical treatment is deficient if an x-ray examination is not ordered.

For a variety of reasons, several investigators now question the routine use of x-ray films following head trauma. These reasons include the doubtful value of the diagnostic information obtained, unnecessary exposure of the patient to ionizing radiation, and an increasing awareness of the cost of x rays and other diagnostic tests.

Between 1964 and 1970, utilization of skull radiography increased significantly. In 1964, it was estimated that 11 million skull radiographs were made in the U.S. (23). If, on the average, each examination consisted of 5 films, then approximately 2.2 million skull x-ray examinations were conducted in 1964. In 1970 (the last year for which national estimates exist) it was estimated that 4.2 million skull x-ray examinations were performed (24). This 90 percent increase in skull radiography occurred over a period when the U.S. population increased by 7 percent (23,24). There is no direct estimate of the number of skull x-ray examinations performed in recent years, but an extrapolation can be made. If the growth rate for skull radiographic examinations between 1970 and 1979 was identical to the growth-rate from 1964 to 1970, then 9.3 million radiographic skull examinations were performed during 1979 (25). As a further note of interest, approximately 85 percent of all skull radiographic examinations were conducted in hospitals in 1964 and 1970 (23,24).

Many believe that a primary reason for the large number of skull examinations performed annually is fear of a malpractice suit (20,21,26). Although reasons such as "difficulty in evaluating the patient," "alleged injury," "doubtful fracture," or to "exclude gross disease" (reassure patient) are given, it has been estimated that up to 34 percent of emergency skull exams (26) may be ordered for medico-legal reasons. It has also been noted that heavy legal sanctions may result when an x ray is eliminated from a diagnostic protocol, while there are currently no penalties for ordering frequent x rays (21,27).

Several authors have condemned these practices. Shopfner and Roberts (28) state, "Medico-legal reasons for skull roentgenography simply to detect fractures are not valid." Roberts echoes this theme, suggesting that thorough patient histories and physicals might lead to fewer x-ray examinations and solve the malpractice problem as well. Legal defense societies have recommended that x rays be ordered only when medical conditions dictate the need (29).

Because overutilization of skull radiography has been suspected for some time, several researchers (18, 26, 30, 31) have conducted studies to assess the utility of skull radiography and have developed lists of clinical signs and symptoms for physicians to use as aids when judging whether or not to order a skull series. These signs and symptoms have been called "high-yield criteria" or simply "referral criteria." The purpose of such criteria is to help physicians distinguish between patients who need a skull series and those who can be properly diagnosed without it. The following sections of this report will discuss the development of referral criteria as well as their efficacy and safety.

## DISCUSSION OF MAJOR ISSUES

### EFFICACY OF SKULL RADIOGRAPHY

The United States Congress and portions of the health community have become concerned about rising medical costs and over-utilization of technology (32). Because funds and personnel for health care are limited, attempts have been made to alter physician behavior and to improve cost-effectiveness in the use of medical resources. This section examines the efficacy or utility of skull radiography for trauma and discusses means to increase the cost-effectiveness of the examination.

#### Definition of Efficacy

The issue of efficacy is difficult to discuss without agreement on an appropriate definition. The following definitions have been reported in the literature.

Potchen (33) has defined efficacy as the employment of a procedure in such a fashion that the resulting data are informative and can "... make a beneficial difference to the patient."

The American College of Radiology (ACR) (34) has defined three separate levels of efficacy:

- Level one efficacy - "refers to the informational content of a procedure, regardless of whether or not the information content had an effect on subsequent management."
- Level two efficacy - refers to the employment of a procedure which alters the proposed patient management by requiring either: (1) reformulation of the treatment plan, or (2) gathering of additional diagnostic information.
- Level three efficacy - results from the use of procedures which, in the long term, benefit the patient's health.

For purposes of this report, efficacy will be synonymous with utility, i.e., a diagnostic test will be considered efficacious if the results, positive or negative, are useful in patient management. If the results of a diagnostic test do not affect patient care, the test will not be regarded as useful. In most cases, knowledge of a negative finding from a skull radiograph does not alter the standard of care. Similarly, the knowledge of a positive finding from a skull radiograph does not always modify patient care.

The term "yield" has been used in the literature in two quite different and distinct ways. Yield, in its simpler form, has been used to refer to the percent of skull x-ray examinations that produce a positive finding, such as a linear or depressed fracture. For example, in St. John's study (16), 1,000 skull series were requested and 150 fractures were detected, for a 15 percent positive yield (see Appendix A). In contrast, yield has also been used to designate the fraction of significant findings, i.e., the fraction of examinations that lead to a change in patient management or have serious intracranial sequelae. In the Harwood-Nash, Hendrick, and Hudson study (5) 4,465 skull series were requested and 143 significant fractures were reported, for a 3 percent yield of significant fractures.

It becomes apparent that the focus of utility studies in skull radiography has evolved from simply increasing the positive yield to maximizing significant yield. Therefore, when appropriate, this report will note these two distinct ways of reporting yield.

## Initial Utility Studies

Some authors (9, 18, 26, 35, 36) have proposed that skull radiographic procedures used at the ACR level one efficacy represent inefficient use of resources. They argue that strategies and efforts should be directed at level two efficacy, where radiographs are taken if they are likely to alter treatment (9, 26, 37-39). Counterarguments state that decreased utilization of a procedure will result in missed abnormalities and possibly increased situations for malpractice suits.

A number of physicians consider the identification of skull fractures to be of paramount importance (40-43). Jennet (44) has noted that undiagnosed compound depressed fractures often lead to intracranial infection which can result in death. Such fractures can be overlooked when the patient may have been unconscious only briefly, and may not have presented with symptoms that would prompt an x ray. Jennet noted that physicians should assume that every scalp laceration may possibly overlie a depressed fracture and every orbital or retromastoid hematoma may possibly signal a fractured base.

Neurosurgeons, whose patients frequently have injuries with complications, assert the importance of diagnosing skull fractures. They contend that secondary complications such as intracranial hemorrhage or infection can evolve even after mild injuries. Furthermore, such complications seldom occur without a fracture (44, 45). Phillips (46), however, in a personal communication, contends that skull radiography does not rule out skull fracture or brain damage. Furthermore, fractures which are clinically significant may be missed, i.e., they may not be apparent in standard views.

Regardless of the extent of correlation between fracture and severity of injury, the basic radiological question remains: to what extent does the knowledge of a skull fracture alter patient management?

St. John (16), an early skeptic of the routine use of skull radiography in head trauma, was among the first to examine the utility of the examination. In a retrospective study of 1,000 cases he discovered 150 positive radiographic findings, one positive examination in every 6.7 requests. This 15 percent yield is considered high when compared to other estimates (10). With the study findings and the knowledge that the life threatening aspects of skull trauma are edema, shock, and intracranial hemorrhage, and not a fractured skull, St. John advocated the use of skull radiographs solely as an adjunct to the clinical exam and never as a routine emergency procedure.

Harwood-Nash, Hendrick, and Hudson (5) also conducted a retrospective study of the use of skull x rays in 4,465 children. The objective was to determine if the presence of a skull fracture increased the likelihood of intracranial damage. They concluded that, although a fracture was frequently associated with brain damage, almost every instance of serious intracranial complications was accompanied by sufficient clinical evidence to make the diagnosis. Further, the absence of a fracture did not negate the possibility of brain damage. The detection, location and type of fracture had no correlation with physical findings and symptoms. Additionally, the presence of a skull fracture as a single indicator was of little significance. The primary purpose of the radiographs should be for detection of the effects and sequalae of trauma on the cranial contents, not for identification of a fracture.

Somewhat later, Eyes and Evans (4) concurred that the low yield of skull radiographs makes them of limited value in the management of head injuries. In a review of 504 patient records, they attempted to correlate presenting signs and symptoms with radiological findings. Nine patients, or one in 56, were radiologically identified as having fractures. A total of 129 patients were admitted to the hospital; eight of these already had radiographically detected fractures. One patient with a fracture was discharged from the emergency room. The results of the study showed no correlation between hospital admissions and scalp hematoma or laceration, headache, or mild concussion. Patients exhibiting symptoms of a central nervous system disturbance were admitted to the hospital. In the nine fracture cases, the majority had observable symptoms, independent of radiographic findings, which

indicated the necessity for hospital admission. Results of the radiographic examinations altered patient care in two cases. Eyes and Evans concluded that the clinical condition and not the detection of a skull fracture is the determinant for hospital admission and treatment and that the plain skull x-ray examination has limited worth in the management of head trauma. (Appendix A summarizes the utility and high-yield criteria studies.)

### High-Yield Criteria

Bell and Loop (26) were among the first researchers to question the use of skull radiographs for routine purposes. However, they went beyond St. John (16) and in 1970 developed a list of 21 hypothesized high-yield criteria for ordering skull x rays (Appendix B). This study of 1,500 patients presenting with head trauma to the emergency departments of University Hospital and Harborview Medical Center, Seattle, Washington, had as its objectives the determination of the yield of skull series, and the development of a rationale for selecting patients who would be likely to demonstrate a high yield of skull fracture.

Bell and Loop reported the occurrence of 93 fractures in 1,500 skull examinations, a frequency of one in every 16 examinations. Their high-yield criteria were met in 10 percent of the examinations. Only one fracture would have been missed if the criteria list had been used as a precondition for the x-ray examination, and 434 examinations (29 percent) would not have been taken. However, no single one of the 21 high-yield criteria was met in the majority of patients with fractures. Twenty-eight of the 93 detected fractures (2 percent of the examinations) necessitated an alteration in treatment plan. Bell and Loop concluded that without the use of the criteria the probability of detecting a skull fracture was low. However, an even lower likelihood existed that the radiographic findings would alter patient management.

Impressed with the data and issues raised in the Bell and Loop study, Phillips (9, 31) recommended that the University of Washington Hospital implement a modified version of Bell and Loop's high-yield criteria list (Appendix C). The suggestion met with some resistance. Therefore, in its place, the policy was instituted that all emergency-room head trauma cases be seen and evaluated by a member of the neurosurgery staff prior to requesting skull radiography. This policy was monitored for one year. During the year, a review committee also checked the clinical indications for skull radiography requests against Phillips' proposed modified high-yield criteria list. The following conclusions were drawn:

- Despite only 55 percent physician compliance with the policy, the number of skull x-ray examinations for trauma decreased 39 percent from the previous year.
- All of the skull trauma patients with positive radiographic reports had presented with the high-yield criteria.
- If 100 percent compliance had been achieved, the number of skull x-ray examinations would have been reduced an additional 45 percent.

As a result of this experience, the high-yield criteria list was again modified (Appendix D). This new list was incorporated into hospital policy for ordering skull x-ray examinations and was monitored for an additional year. The following observations were made:

- Skull radiography utilization remained at about 60 percent of the pre-policy utilization rate.
- A physician compliance rate of only 50 percent again demonstrated the reluctance of Emergency Department physicians to use the criteria list.
- The most commonly met criterion was "loss of consciousness." Sixty-seven examinations were requested for this reason; of these cases, 57 were regarded as

demonstrating a questionably unconscious condition or were unconscious for less than 5 minutes.

Because of the data collected from these two observation periods, the criteria list was once more revised. The unconsciousness criterion was restricted to only those patients with an "established history of unconsciousness" and thus the list was reduced to 11 criteria (Appendix E). This modified list became the hospital policy for ordering skull x-ray examinations in the Emergency Department of University Hospital beginning in August, 1976.

Additional studies were conducted by Phillips. In a subsequent study, he compared the utilization rate at the Harborview Medical Center (HMC), which had no formal criteria for requesting skull x-ray examinations, with University Hospital (9,31). Data acquired over a 1-year period showed that the skull radiography utilization rate at HMC exceeded that at University Hospital by a factor of 6.4. During this time, 258 skull x-ray examinations were requested at University Hospital as compared to 2,275 requests at HMC. Eighteen positive reports were made at University Hospital. Nine of these reports provided information that altered the care of the patient, i.e., one significant examination for each 29 examinations performed. At the Harborview Medical Center, 114 positive reports were made and 51 contributed to the management of the patient. The Harborview result represents one significant report in every 45 examinations performed.

Phillips (31, 39, 47) attempted a followup study in which the high-yield criteria list and monitoring program would be employed at both the University Hospital and HMC. He demonstrated a 26 percent decrease in the utilization rate at HMC. Of 1,472 total requests for skull radiography, 73 of the 107 positive reports, all emanating from the group of 265 in which high-yield criteria were documented, made a contribution to patient management. This can be converted into one significant examination in every 20 examinations. Within the high-yield group only, the number of significant outcomes was 1 in every 4 examinations. There were 1,207 skull x-ray examinations made in the group without documented evidence of high-yield criteria. None of the reported 79 positive findings in this group altered patient care. Thus, one could say that all 1,207 individuals in the "without high-yield criteria group" were exposed to a nonbeneficial skull x-ray examination as compared to 158 negative reports in the "high-yield criteria group."

At the University Hospital a total of 117 skull examinations were requested. From these, a total of six cases were found where patient care was altered. All six cases were in the documented high-yield group, for a yield of one significant examination in every 20 exams. There were 79 cases receiving skull radiographs in the group that did not have high-yield criteria; no significant contributions which altered patient management were found, but 77 negative findings were reported. Phillips concluded that implementation of a policy of using high-yield criteria in conjunction with a monitoring program can influence skull radiography utilization in emergency facilities, even with only voluntary compliance. He further noted that a medical-record based evaluation of the efficacy of skull radiography for head trauma indicated that approximately 80 percent of all the examinations in both facilities in this study did not make a significant contribution to patient care (31, 39, 47).

One limitation of Phillips' studies was poor physician compliance with the policy. Despite the documented reduction in requests for skull radiography, problems were encountered in gaining physician cooperation. One possible reason for the noncompliance was the medico-legal factor. Although Phillips has argued against medical malpractice as being a real and substantive issue, the threat of malpractice suits certainly is present in the minds of emergency room physicians and can significantly affect their ordering habits. Such medico-legal considerations will be discussed in more detail later.

indicated the necessity for hospital admission. Results of the radiographic examinations altered patient care in two cases. Eyes and Evans concluded that the clinical condition and not the detection of a skull fracture is the determinant for hospital admission and treatment and that the plain skull x-ray examination has limited worth in the management of head trauma. (Appendix A summarizes the utility and high-yield criteria studies.)

### High-Yield Criteria

Bell and Loop (26) were among the first researchers to question the use of skull radiographs for routine purposes. However, they went beyond St. John (16) and in 1970 developed a list of 21 hypothesized high-yield criteria for ordering skull x rays (Appendix B). This study of 1,500 patients presenting with head trauma to the emergency departments of University Hospital and Harborview Medical Center, Seattle, Washington, had as its objectives the determination of the yield of skull series, and the development of a rationale for selecting patients who would be likely to demonstrate a high yield of skull fracture.

Bell and Loop reported the occurrence of 93 fractures in 1,500 skull examinations, a frequency of one in every 16 examinations. Their high-yield criteria were met in 10 percent of the examinations. Only one fracture would have been missed if the criteria list had been used as a precondition for the x-ray examination, and 434 examinations (29 percent) would not have been taken. However, no single one of the 21 high-yield criteria was met in the majority of patients with fractures. Twenty-eight of the 93 detected fractures (2 percent of the examinations) necessitated an alteration in treatment plan. Bell and Loop concluded that without the use of the criteria the probability of detecting a skull fracture was low. However, an even lower likelihood existed that the radiographic findings would alter patient management.

Impressed with the data and issues raised in the Bell and Loop study, Phillips (9, 31) recommended that the University of Washington Hospital implement a modified version of Bell and Loop's high-yield criteria list (Appendix C). The suggestion met with some resistance. Therefore, in its place, the policy was instituted that all emergency-room head trauma cases be seen and evaluated by a member of the neurosurgery staff prior to requesting skull radiography. This policy was monitored for one year. During the year, a review committee also checked the clinical indications for skull radiography requests against Phillips' proposed modified high-yield criteria list. The following conclusions were drawn:

- Despite only 55 percent physician compliance with the policy, the number of skull x-ray examinations for trauma decreased 39 percent from the previous year.
- All of the skull trauma patients with positive radiographic reports had presented with the high-yield criteria.
- If 100 percent compliance had been achieved, the number of skull x-ray examinations would have been reduced an additional 45 percent.

As a result of this experience, the high-yield criteria list was again modified (Appendix D). This new list was incorporated into hospital policy for ordering skull x-ray examinations and was monitored for an additional year. The following observations were made:

- Skull radiography utilization remained at about 60 percent of the pre-policy utilization rate.
- A physician compliance rate of only 50 percent again demonstrated the reluctance of Emergency Department physicians to use the criteria list.
- The most commonly met criterion was "loss of consciousness." Sixty-seven examinations were requested for this reason; of these cases, 57 were regarded as

demonstrating a questionably unconscious condition or were unconscious for less than 5 minutes.

Because of the data collected from these two observation periods, the criteria list was once more revised. The unconsciousness criterion was restricted to only those patients with an "established history of unconsciousness" and thus the list was reduced to 11 criteria (Appendix E). This modified list became the hospital policy for ordering skull x-ray examinations in the Emergency Department of University Hospital beginning in August, 1976.

Additional studies were conducted by Phillips. In a subsequent study, he compared the utilization rate at the Harborview Medical Center (HMC), which had no formal criteria for requesting skull x-ray examinations, with University Hospital (9,31). Data acquired over a 1-year period showed that the skull radiography utilization rate at HMC exceeded that at University Hospital by a factor of 6.4. During this time, 258 skull x-ray examinations were requested at University Hospital as compared to 2,275 requests at HMC. Eighteen positive reports were made at University Hospital. Nine of these reports provided information that altered the care of the patient, i.e., one significant examination for each 29 examinations performed. At the Harborview Medical Center, 114 positive reports were made and 51 contributed to the management of the patient. The Harborview result represents one significant report in every 45 examinations performed.

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## Additional Utility Studies

Roberts and Shopfner (28) investigated the utilization of skull radiographs in 570 children. Their study demonstrated a fracture yield of 8.6 percent. Patient management was affected in only two cases, resulting in 1 significant exam for each 285 performed. The detection, location, and type of fractures showed no correlation with symptoms and physical findings. The presence or confirmation of a fracture, not necessarily accompanied by symptoms or physical findings, corresponded to an increase in hospitalization. However, non-fracture patients hospitalized because of symptoms and physical findings equaled the number of patients hospitalized for fracture. Regardless of fracture, hospitalization was correlated with the combination of bleeding from the ear and positive neurologic findings. Treatment was related only to symptoms and physical findings; it was unaffected by the detection of a fracture.

The authors believed that two questions need be asked regarding the use of skull radiography: (1) does the radiographic finding contribute to treatment; and (2) can yield be improved by patient selection? From their results it is apparent that fracture detection influenced hospitalization, but did not influence patient care except in situations of depressed fractures or the presence of foreign bodies. The best radiographic yield resulted from patients having bleeding from the ear, positive neurologic findings, and severe symptoms. Roberts and Shopfner suggested the following factors as the basis for patient selection: history, physical examination, symptoms, and the physician's clinical evaluation. In conclusion, they believed that the results of their study and Bell and Loop's suggested that the routine use of skull radiography is unjustified in cases of head trauma. In a later study, Obisesan and Bohrer (48) confirmed the findings of Roberts and Shopfner.

Jergens, Morgan, and McElroy (49) conducted a study similar in objective and methods to that of Bell and Loop. During a 5-month period, 847 skull examinations were made and 21 skull fractures were reported, for a 2.5 percent yield. The participating physicians were asked to estimate the probability of a fracture being present for each skull radiography request. The probability estimates were broken down into three groups: under 10, 50, and over 90 percent. In the group where the indicated probability of skull fracture was less than 10 percent, only 0.8 percent had fractures out of a total of 761. In the group where a 50 percent estimate was given, there were 8.5 percent positive findings out of 71 requests. In the over 90 percent group, 60 percent of 15 examinations demonstrated fractures. Eight of the total 21 detected fractures required a change in patient treatment. In each of these eight cases, patient care was modified because of the neurologic examination, not the radiographic finding. The investigators believed the study supported the concept that concern should first be addressed to the patient's mental and neurologic status rather than the existence of a fracture. The study verified the yield found by Bell and Loop and confirmed that a radiographic finding of a fracture was not of assistance in determining outcome. In support of referral criteria, Jergen et al. reported that in the absence of criteria such as a history of decelerative force, loss of consciousness or other neurologic problem, or a palpable tenderness on skull examination, the likelihood of a significant finding is decreased.

In another attempt to confirm the utility of Bell and Loop's high-yield criteria, De Smet, Fryback, and Thornbury (8) conducted a prospective, 11-month study on a population group of mixed ages. Of 594 cases studied, 17 skull fractures (2.9 percent) were radiographically reported. Seven of the 17 reported fractures failed to show the presence of any of the high-yield criteria, and thus would have gone undetected. The ages of these seven patients were recorded as ranging from 2 months to 16 years. Six of these seven received the standard care and did not require further treatment. The remaining individual was selected for radiography because of a clinical manifestation not appearing on the high-yield criteria list. Comparing their results to those of Bell and Loop, the authors noted the following differences: (1) a lower incidence of fracture; (2) a larger proportion of undetected fractures; and (3) a lack of significant association between the high-yield criteria and the existence of a fracture. One reason given by the authors for these differences was that the study population contained a greater proportion of pedriatric patients. Bell and Loop had previously

surmised that their criteria might need to be altered for children. In conclusion, De Smet et al. suggested the necessity of testing the high-yield criteria in populations different from that originally used by Bell and Loop, and focusing research on the treatment outcomes subsequent to noting a skull fracture. Goldstein et al. (50) also commented on the differing response of children to skull injuries.

A study performed by Masters (18, 36) recommended the use of high-yield criteria to detect significant intracranial sequelae resulting from head trauma. The retrospective study was designed to determine whether plain skull films influence patient management or affect long-term outcome in patients sustaining head trauma. The review of 1,845 patient records showed that 79 fractures were identified, or one out of 23 examinations resulted in a positive finding. Thirty-three patients (1.8 percent) were noted as having significant intracranial sequelae. Seven of the 33 patients had sustained skull fractures; five were simple, one depressed, and one was a basilar fracture. Masters found that of the total of 79 skull fractures, there were 12 depressed and seven basilar fractures. If all seven basilar fractures were diagnosed solely by radiography, then skull films would have affected patient management in less than 1 percent of the sample, a significant yield of 0.38 percent. Therefore, Masters concentrated his efforts toward devising clinical predictors which would render high yields in identifying skull fractures with the likelihood of significant intracranial damage. High-yield criteria similar to Phillips' (Appendix F) were utilized.

Masters' efforts differed from Phillips' in that he did not focus on fracture identification as an endpoint, but rather, attempted to redirect clinical thinking toward signs of intracranial injury. He found that the physical and history criteria generally demonstrated low predictive value for both skull fractures and significant intracranial sequelae. However, the neurologic criteria were high predictors for significant intracranial injury. Concerning depressed or basilar fractures, Masters suggested additional studies prior to devising high-yield criteria. Therefore, he and others (51) have suggested studies be conducted to develop criteria for identifying skull trauma patients with these types of fractures and those incurring significant intracranial damage. In the absence of such criteria, however, Masters suggested CT as the procedure of choice for those patients presenting with any clinical suspicion of intracranial injury. He concluded that the routine use of skull radiographs in the diagnosis of skull fracture has no appreciable effect on the management or outcome of acute brain injury.

Lawaetz (52, 53) undertook two studies investigating the use of skull radiographs in head trauma. One study was of 3,521 patients presenting with head injuries at emergency departments. The second was of 952 hospitalized head trauma patients. He followed the latter group from 1 to 2 years to note the emergence of sequelae. Because skull radiographs produced low yields in both groups, he suggested they be discontinued as an assessment procedure in casualty departments and as a predictor of sequelae for hospitalized patients.

In another study, Larsen and Koziol (54) reported on a retrospective analysis of 75 patients admitted to two hospitals in Northern Virginia. The study revealed that 36 skull fractures would not have been diagnosed if high-yield criteria had been used to select patients for skull radiography. Thirty-two of the potentially missed fractures were linear and four were depressed. One of the linear and the four depressed fractures required operative intervention. The authors concluded that, based on this experience, the criteria were unacceptable. They recommended additional testing of the criteria.

In response to the Larsen and Koziol study, the journal which published the study received several letters-to-the-editor which commented on the study's weak points (55). The study was faulted mainly for the methodology employed and for the lack of data regarding the missed fractures, specifically the five requiring surgical intervention. The critics questioned a methodology that retrospectively reviewed records for the presence or absence of criteria which were not previously given to the emergency room physicians. The results attained may have been a function of poor chart recording. In summary, those commenting on the study share the opinion that the conclusions noted by Larsen and Koziol are not supported by their methodology.

Cummins and LoGerfo (56) conducted a study to determine: (1) the performance of a high-yield criteria list as a screening test; (2) if adverse outcomes resulted from the use of the criteria list; and (3) whether the list changed physician performance. The study design consisted of a before-and-after approach with the intervention of the high-yield criteria list at the midpoint of the study. In essence, the subjects served as their own controls. Measurements were made prior to intervention and subsequent to it. The differences were then noted. Using the criteria list, 962 skull films were made and 67 were reported as positive. The criteria list was reported to be sensitive at .925, or capable of accurately predicting 62 out of 67 fractures. Among the 761 patients classified as negative, five fractures were missed using the list. The criteria list's predictive value of being negative on all nine of the criteria was .993 and the predictive value of being negative on any one of the criteria was .31. Physicians demonstrated a significantly decreased use of skull radiography after the implementation of the criteria list. The number of patient visits for head trauma remained the same; however, requests for skull radiographs decreased by 40 percent.

Interviews of a sample of the participating physicians demonstrated that the observed behavioral changes were due to increased awareness of the criteria, knowledge that their performance was being monitored, and the inconvenience associated with the forms used to request skull radiographs. These findings are tentative and can be faulted by the methodology employed because the two sets of data were gathered from two different groups of physicians. Consequently the validity of the conclusion can be questioned.

In an attempt to discern any adverse outcomes from the decreased use of skull radiographs, one-fourth of the non x-rayed patients were randomly selected for followup and chart review. The chart review demonstrated no adverse outcomes, such as unscheduled followup visits or subsequent death. It was found that if a high-yield criterion was not present, a fracture, pineal shift, or intracranial injury would be unlikely. The authors concluded that the rate of adverse outcomes would not be greater than 0.02 at a 95 percent confidence level. Although the rate of adverse outcomes was small, the authors thought there was appropriate concern that such outcomes may occur in the non x-rayed trauma patient. A review of the five false negatives (missed fractures) showed that no change would have been implemented in patient management except for one patient who chose to postpone elective surgery. The authors noted that the use of high-yield criteria resulted in an increased yield of radiographically detected fractures, which rose from five to 12 percent. Several study limitations prevent generalizations. Yet the investigators concluded that, in head trauma without one of the high-yield criteria present, the possibility of a fracture or intracranial damage was slight. However, they urged additional testing of the use of guidelines in specific age groups and populations differing from those of the emergency room. They also acknowledged that the low positive yield of skull radiography does not necessarily render it inefficacious. They contend that negative radiographic findings may also be diagnostically efficacious to the physician, for they often are the basis for disposition policies and assist in "ruling out" various disease possibilities.

Recently, Freed (57) recommended that two more criteria be added to the Phillips list: "skull penetration suspected," and "presence of coma or stupor not clearly due to alcohol or drug ingestion." He claimed that the former criterion would raise physician sensitivity to these injuries, in addition to picking up serious fractures which would otherwise be missed. Freed questioned the applicability of the complete criteria list to children and suggested further research in this area. He also advocated additional data collection on such possible criteria as 5-minute retrograde amnesia, semi-consciousness at the time of examination (particularly in children), and cases in which the examining physician thinks the probability of a fracture is "50:50" or "9:1 certain."

The results of Phillips' study comparing utilization rates at the University and Harborview Hospitals were published in a BRH Report in July 1978 (9). A short article describing Phillips' work and listing the criteria was also published in the FDA Drug Bulletin, October - November 1978 (58). An article listing the high-yield criteria appeared in the journal, Neurosurgery (58a). Subsequently, Arden F. Reynolds, in a letter to the editor of Neurosurgery (59), alleged that while he was a neurosurgical resident at the University of

Washington Hospital, five patients died because of failure to obtain skull films. He asserted that the decision to forego films resulted from the absence of any of the high-yield criteria in these patients. In subsequent correspondence with the Bureau of Radiological Health, Reynolds clarified that 3 of the 5 deaths occurred at Harborview Hospital but he was unable to recall the patients' names or the dates of these three incidents. He also was unable to recall the name of one of the two alleged patients at the University of Washington. The one named case was investigated and the case records did not bear out the allegation.

As a result of this allegation, the Bureau of Radiological Health took two specific actions to ascertain whether the formerly unreported deaths at Harborview could be attributable to the use of high-yield criteria.

- The allegation made by Reynolds was investigated by the University of Washington under an existing FDA contract. A review of 12,639 reports identified three cases that seemed to correlate with the circumstances Reynolds had described. However, in one or two of these cases it appeared likely that high-yield criteria were met, so that failure or delay in obtaining radiographs may have been due to other factors. (For a summary of the cases, see Appendix G.) From the review of these records, the study investigators recommended the inclusion of an additional criterion relative to the alcoholic patient. The investigative committee concurred that an alcoholic presenting to an emergency room for head trauma and in a state of agitation warrants skull radiographs. The committee believes the high-yield criteria should serve as a helpful adjunct to clinical assessment and patient observation, as well as an aid in the selection of patients for skull radiography. Phillips (personal communication, 1980) contends that no case would have been managed inappropriately if the following high-yield criteria had been utilized: (1) unconsciousness (including cases of unarousable alcoholics) or a documented decreasing level of consciousness at the time of arrival at the emergency facility after metabolic seizure disorders are excluded as the cause of unconsciousness; (2) skull depression, palpable or identified by probe through laceration or fracture wound; and (3) unexplained focal neurological signs.

- A large-scale, multi-center contract was awarded to assess risks that may be associated with the use of skull x-ray criteria (46).

Phillips (30, 46), in continuing support of the use of high-yield criteria, recommends that skull films not be taken when skull trauma patients initially present to the emergency room. Instead, he suggests that, if clinical evaluation identifies any of the three criteria above, cranial computed tomography (CT) be requested. Phillips suggests that skull radiography be conducted only when necessary to confirm the findings from computed tomography. Masters (personal communication, 1980) disagrees; he thinks requesting CT based on high-yield criteria for fracture will result in an overutilization of CT. Instead, he suggests that requests for CT be based on high-yield criteria for significant sequelae.

Vydareny, Harle, and Potchen (10), in agreement with Phillips, conducted a study comparing the use of skull radiographs and computed tomography. An algorithm for the use of CT was developed. Based on the results of the CT scan, a skull radiograph was sometimes requested. A retrospective review of the effectiveness of this algorithm was made. A pre-criteria baseline count of 335 skull radiography films and 25 CT scans was reported. The developed criteria would have decreased the number of skull films to 32 and increased the CT scans to 39.

In summary, the contribution of plain skull radiography in the management of head trauma has been a subject of interest for over 20 years. Many authors believed that skull radiographs were ordered for even the most trivial injuries and that something could be done about unnecessary utilization. Early attempts sought to better define those patients for whom skull radiography could provide useful diagnostic information. Criteria were developed to identify patients likely to have positive diagnostic results; these were called "high-yield criteria." High-yield criteria were shown to reduce significantly the ordering of skull

radiographs in a few well-circumscribed emergency room settings. In such settings, the criteria were successful in separating out a subset of patients whom skull radiography might benefit, without any apparent adverse consequences on other head injury patients.

More recently, as attempts have been made to use high-yield criteria in different clinical settings, it has become apparent that the criteria may not have general applicability. For example, criteria developed in a primarily adult population may not apply in a patient population made up mainly of children. Furthermore, several issues have been pointed out in the literature which must be addressed before high-yield criteria can be applied widely. First, only limited followup has been done to assess outcomes of patients who are not radiographed when high-yield criteria are used. Second, several studies have shown that finding a skull fracture frequently has little impact on patient management and that the finding of a simple linear fracture does not correlate well with significant sequelae. Such authors have noted that it is more important to use a criteria list for defining those patients in whom significant sequelae would be expected. Finally, physician acceptance in terms of using the criteria has not been high even in situations where rather tight controls have been applied.

In light of the information obtained from the literature, additional work might be guided by the following suggestions:

(1) Research regarding the use of high-yield criteria in skull radiography, particularly for basal and depressed fractures, should be continued.

(2) Additional research should include a broader population base and a wider variety of clinical settings.

(3) Assessment of the risks of using high-yield criteria should be encouraged.

(4) Flexibility must be maintained in the use of high-yield criteria. The criteria list should be modified by accounting for differences in geographical regions or population demographics, as well as new knowledge and technologies.

(5) Research in the use of high-yield criteria for predicting significant intracranial sequelae should be continued.

(6) Studies should be encouraged to develop high-yield criteria for ordering CT examinations following skull trauma and to examine the utility and cost of such criteria.

## COMPUTED TOMOGRAPHY (CT)

The introduction of computed tomography (CT) in 1972 represented a major breakthrough in the assessment of head injuries. CT findings in acute trauma include general and focal cerebral edema, contusion, intracerebral or extracerebral hematomas, subarachnoid and intraventricular hemorrhage (60) and shearing type injury of the cerebral white matter (61). Furthermore, a CT scan can be taken promptly after presentation to the emergency room and is a non-invasive technique, whereas cerebral angiography and ventriculography are invasive procedures with attendent risks and require considerable time to set up. In a review of the CT findings in 286 patients with acute head trauma, Zimmerman et al. found an 84 percent reduction in cerebral angiography and a 58 percent reduction in surgical intervention. In the case of an acute intracerebral hematoma, CT can clearly indicate the site and size of the hematoma. For patients with acute nonpenetrating cerebral injury, CT is especially useful in identifying those patients who can benefit from surgical intervention (61). Additionally, it can obviate the need for invasive diagnostic procedures which could have a deleterious effect on the already labile condition of the patient. Zimmerman et al. found that, if bilateral cerebral swelling is recognized and treated promptly in pediatric patients, the possibility of complete recovery may be as high as 90 percent.

The epidural hematoma is a life-threatening condition which is often amenable to surgical correction. By avoiding the delays and risks encountered with angiography, CT permits more rapid and accurate identification of these lesions. This is especially important in the case of an epidural hematoma when the patient may be temporarily asymptomatic while the extracerebral life-threatening mass expands. In the study by Zimmerman et al., prompt surgical evaluation of the epidural hematoma resulted in 100 percent post-operative survival with a mortality rate of 7 percent thereafter. Jamieson and Yellard reported a mortality of 15.6 percent for epidural hematomas in the pre-CT era (62).

CT is superior to a routine skull series in identifying significant craniocerebral damage following skull trauma (60,63). Skull films are obtained to detect skull fractures or the displacement of a calcified pineal gland. A displaced pineal gland may indicate the presence of a hematoma. A skull series cannot directly detect hematoma, edema or contusion. The displacement of the pineal gland can be detected if the gland happens to be calcified. However, only about 55 percent of adults have obvious calcification of this gland (64). Furthermore, the pineal gland may be off the midline due to factors other than a hematoma. CT easily and accurately defines all these conditions.

A normal radiographic skull series is not 100 percent accurate in detecting skull fractures. Even if it were possible to detect all skull fractures, there seems to be little correlation between a skull fracture and significant neurological damage. For example, Zimmerman et al. (61) found that 32 percent of the patients in their study who had normal skull films had significant intracranial abnormality demonstrated by CT. On the other hand, skull films were positive for 28 percent of the patients in whom there was no significant intracranial abnormality on CT.

Preliminary or screening skull films, even if they are normal, do not decrease the need for further diagnostic series; at most, they may indicate the need to employ angiography if CT is not available. For these reasons, a number of radiologists regard CT as the procedure of choice not only for patients presenting with head trauma but for a general neurological examination as well (30, 46, 65, 66).

## OTHER ISSUES

### COST TO PATIENTS FROM OVERUTILIZATION

If the skull x ray is medically indicated, it is assumed that the anticipated benefit outweighs any risk associated with the radiographic procedure. However, if the x ray is not indicated, the patient sustains a burden in terms of radiation insult and also in terms of financial costs.

#### Radiation Considerations

The radiation effects on the patient are both genetic and somatic. The genetic effect is measured in terms of the gonad dose and the Genetically Significant Dose (GSD). The GSD is an index of the presumed genetic impact of radiation exposure on the whole population. The estimated mean gonad dose per examination from skull radiographic examinations in 1970 was less than 0.5 millirad (71). The estimated contribution to the GSD from skull radiographic examinations in 1970 was less than 0.05 millirad (71). No estimate has been made of the GSD since 1970. Data from the Nationwide Evaluation of X-ray Trends (NEXT) indicate that the mean gonad dose from the lateral skull projection is less than 0.5 millirad per film (72). Hence, it is not likely that the genetic effects from skull examinations have increased since 1970; if anything, they may have decreased due to improved techniques. The genetic dose from plain film skull examinations is, therefore, not considered significant.

The organ systems at risk from a skull examination are the active bone marrow in the skull and the thyroid gland. The possible somatic effects from radiation exposure to these organ systems are leukemia and thyroid cancer, respectively. The estimated mean active

bone marrow dose per skull examination was 78 millirads in 1970 (73). The mean active bone marrow dose is a measure of the amount of energy which would be deposited in the total body bone marrow by a uniform exposure of the entire body. The actual dose to the active bone marrow in the skull is, of course, much higher.

The estimated thyroid dose from the lateral skull exam is 79 millirads, according to NEXT data for 1978. The dose to the thyroid gland depends upon the skull projection taken. Using data from Rosenstein, it is estimated that a skull series consisting only of AP, lateral, and PA projections would deliver a dose of approximately 200 millirads to the thyroid gland (74).

The calculations to estimate the possible increased incidence of thyroid cancer and leukemia due to skull radiography are shown in Appendix H. Based on the assumptions stated there, 3 additional cases of leukemia would theoretically occur as a result of the three projections shown. The latent period between exposure to radiation and the onset of leukemia is approximately 10 years (75). Since leukemia is usually fatal (75), one can expect a corresponding increase in the number of deaths attributed to leukemia.

Appendix H also shows an incidence of approximately 78 additional cases of thyroid cancer due to the dose absorbed by the thyroid gland from the three projections shown. Since thyroid cancer is fatal in about 10 percent of cases (75), one would expect approximately 8 additional deaths due to radiation-induced thyroid cancer. The latent period for thyroid cancer is approximately 25 years (75). These estimates of the incidence of leukemia and thyroid cancer are for individuals exposed to skull x rays in the United States during 1970.

The risk coefficients used in Appendix H are based on a linear extrapolation from whole body doses greater than 100 rads. The risks from low doses to only a portion of the body are likely to be substantially lower (75). The incidences of leukemia and thyroid cancer derived here are based on mean-risk coefficients and are not age-specific. According to these calculations, skull x-rays (trauma and nontrauma) would result in approximately 11 additional deaths from leukemia and thyroid cancers beginning after their respective latent periods.

The incidence of cancer that could theoretically have been avoided in 1970 by eliminating all skull x rays for trauma is less than 81 cases because it is estimated that skull x rays for trauma comprise approximately 60 percent of total skull radiography. However, it must be recalled that these skull x rays were taken on patients who presented with a history of head trauma at the very minimum and perhaps clinical signs and symptoms as well. If one assumes that 60 percent of the skull exams are for head trauma and 40 percent of them could be eliminated by employing more judicious ordering patterns, then approximately 19 cases of thyroid cancer and leukemia could have been eliminated if referral criteria were used for ordering skull radiographs for trauma in 1970.

### Economic Considerations

The number of skull x-ray examinations performed in the U.S. was 4.2 million in 1970 (24). Earlier in this paper it was estimated that 9.3 million skull x-ray examinations were performed in hospitals during 1979. If one assumes that 60 percent of these examinations were ordered following trauma and that 40 percent of those could be eliminated by using referral criteria (30, 31), then 2.2 million skull x-ray examinations could be eliminated. At an average cost of $50 per skull series (32), the use of referral criteria could reduce the national cost for skull radiography by approximately $110 million.

The cost of skull radiography can also be considered from another standpoint. In a study by Roberts and Shopfner involving 570 children with head trauma, the cost of each fracture demonstrated was $291. The cost of each examination that affected clinical management was $7,225 (28). If one assumes an annual inflation rate of 8 percent, these costs would be increased by a factor of two in 1981. Fewer routine skull examinations would also reduce

the workload in the radiology department. The same study by Roberts and Shopfner estimated that each fracture utilized 11.6 hours of working time in the radiology department and each significant fracture required 285 hours. A reduced workload would allow more time for film interpretation and consultation with referring physicians.

Because of its ability to accurately detect and localize various tissue injuries within the brain and extravascular accumulations of blood (61), computed tomography (CT) may well become the procedure of choice for skull trauma (76). At least one hospital emergency department, the University of Washington Hospital, recommends that CT be ordered for patients who present with a history of head trauma and one of the criteria listed on page 11 (as related in Phillips' 1980 personal communication).

CT can produce significant dollar savings by replacing invasive procedures such as angiography and pneumoencephalography which would normally require hospital admission. Data from a study by Worttman et al. in 1975 (77) indicated that the average saving due to avoiding angiography, pneumoencephalography and hospital admission was $1,417 per outpatient. Likewise, the precise information supplied by CT can shorten the length of required hospitalizations.

## MEDICO-LEGAL ASPECTS

Those who contend that skull radiography is overutilized, and who consequently have attempted to reduce its use, have had difficulty obtaining physician compliance, partly because of the issue of medical liability (9, 39).

McClenahan (21), commenting on excessive utilization of radiology, notes that some x-ray examinations are employed to exclude doubts and that heavy legal penalties may be incurred by anyone who fails to order an x-ray examination regardless of the insignificance of the injury or illness. McClenahan and Hall (20) argue that many examinations are routinely performed because lawyers, hospitals, and insurance companies demand them. Phillips and others (9,20,32) attribute present radiography utilization patterns, particularly for skull radiography, to the increasing insecurity of physicians as a result of proliferating malpractice suits. "The requesting of more skull films somehow is felt to protect the physician from the malpractice menace, as it is the accepted community standard of practice" (9). The issues at the heart of the medico-legal controversy are suggested in that statement. Does the taking of a radiograph alter one's risk of liability? Does the failure to take, or the decision not to take, a radiograph also alter one's liability?

Presently, definitive answers to these questions do not exist. The taking of a radiograph and the receipt of a negative report does not absolutely protect one from liability because pathology may be present and not be seen at the time (78). Not taking a radiograph may result in a liability suit if injuries which would have been visible on a radiograph should subsequently develop or progress.

A definition offered for defensive medicine (34, 79) is "the use of diagnostic procedures which are not intended to help the patient but instead serve to protect the physician from physicians stresses the practice of defensive medicine even though it may result in a waste of resources. Bell and Loop (26) express it even more strongly, "...physicians fear that for not discovering a clinically occult fracture they are liable to malpractice suits sufficiently harassing and costly to justify virtually endless medically unindicated examinations."

There are two types of defensive medicine. Positive defensive medicine is the providing of medically unjustified care for the purpose of reducing the possibility of a malpractice suit (80-83). Negative defensive medicine entails the avoidance of a potentially beneficial procedure because of an associated risk of malpractice litigation (80-83). Each of these processes is alleged to have its own unique impact on the health care delivery system. The former type is alleged to be a major factor in the cost crisis in medical care. The rationale for this belief stems from the use of medically unnecessary, and consequently overutilized,

procedures which ultimately add to the cost of health care (80-83). On the other hand, this process supposedly has an attendant and favorable effect on the quality of care rendered. However, it may also reduce the quantity of care provided by the health care system (80). In contrast, negative defensive medicine is thought to have a minimal effect on health care costs. Yet, it may compromise the quality of care provided (81-83). These contentions have not been validated.

There are numerous circumstances and sites in which defensive behavior is likely to occur with greater frequency; for example, in emergency departments staffed by physicians inexperienced in the diagnosis and treatment of trauma (79, 84, 85). The exact extent of these practices is not known.

Efforts have been made to quantify the scope of defensive radiology, in general, and defensive skull radiology, in particular. There are few good studies documenting the prevalence of defensive medical practices, and those studies which have been conducted have created more controversy than agreement (83).

Some physicians think the practice of defensive ordering of x-ray examinations is minor. However, Roberts and Shopfner (28) suggest that skull radiographs are taken both out of habit and for medico-legal reasons. Pilling (92) and Eyes and Evans (4) hold similar views. Hall (20) states that the objectivity and permanence of radiographs provides a disproportionate influence in legal judgments. He contends that these attributes are of particular value in trauma cases where there may be doubt of fracture or alleged injury.

Shanks (86) reports an estimate that 50 percent of x-ray examinations are made for medico-legal purposes. An officer of Blue Shield of California places unnecessary x-ray examinations, laboratory tests, and consultations at the 30 - 40 percent level (87). Hall (20) and Abrams (22) report similar estimates. Others believe that 1/5 of all x-ray examinations are taken for medico-legal reasons and that 1/3 of the skull radiographs are for defensive purposes (88).

Numerous opinion surveys have also been conducted on the subject. One such survey was conducted to determine the manner in which professional liability had affected practitioners in the American Academy of Pediatrics. Fifty percent of respondents said they were ordering more x rays than they had in the past (87). Another survey randomly queried physicians' actions directed at reducing the chance of a malpractice suit. Eighty percent of the 1,400 respondents indicated they were taking specific actions directed at minimizing this probability. The American Medical Association also surveyed a sample of its membership. Seventy-six percent of the 111 respondents indicated they were practicing defensive medicine (83).

The scope of medical malpractice was also examined by the Commission on Medical Malpractice, in 1973 (82, 89). The Commission was not able to define the extent of defensive medicine. A study conducted by the Duke Law Journal concluded that the threat of malpractice does induce physicians to overutilize diagnostic tests. However, the survey concluded that the practice was not extensive and probably did not contribute to increased health care costs (80, 81, 83).

In a study conducted by Garg, Gliebe, and Elkhatib (81), physicians were asked to document in a diary the ordering of diagnostic tests and procedures. The primary reason for ordering each test was also recorded. The findings indicated that 14 percent of x-ray examinations were requested for defensive purposes. Overall, more x-ray examinations than laboratory tests were ordered for this reason, 14 percent versus 9 percent. These results were in agreement with those of the Duke survey.

Bell and Loop (26) first examined the use of skull radiographs for medico-legal reasons. From their questionnaire they ascertained that skull x-ray examinations were requested primarily because of: 1) definite likelihood of a fracture (32 percent); (2) difficulty in evaluating the patient's condition (31 percent); (3) medico-legal considerations (34 percent);

and (4) a request by the patient or a relative (3 percent). Only 2 percent of all fractures were detected in radiographs taken primarily for medico-legal reasons.

A study replicating Bell and Loop's concluded that 19 percent of skull examinations were ordered for medico-legal purposes (49). In most of these patients, there were no suspicious findings at the clinical examination which indicated the need for radiographs.

Phillips (39) referred to estimates that 15 to 34 percent of all emergency facility skull radiographs are done for medico-legal reasons. He noted, however, that an in-house study of Aetna claim files failed to identify a single case that resulted in a suit because a physician failed to take skull films. Pilling (92) reported similar results.

Lusted (34) reviewed the records of 8,658 patients who had radiographs taken in an emergency room setting. He showed that 6.1 percent of all the radiographs studied were taken primarily for medico-legal reasons. A breakdown of the findings indicated that 14.3 percent of skull radiographs were for defensive purposes. This result was second to that of cervical spine at 19.4 percent.

It is obviously difficult to determine the exact scope of defensive medicine. This is partly due to the lack of a definition of what comprises the standard of care for a specified condition. Substantial arguments concerning defensive medicine are correlated with the range of disagreement about standards of medical care (83).

Tancredi (83) maintains that attention to standards focuses on the processes of practice instead of the outcome of medical intervention. Malpractice issues tend to evaluate providers in terms of how their diagnostic and therapeutic skills compared to those of other physicians in their locality or specialty (83, 90). The standard of care is the level of care practiced by other members of the specialty and recommended in scientific publications and statements and position papers of appropriate medical societies or groups (91). This definition also applies to the practice of radiology. Some authors (92, 93) believe the radiology standard of care is a result of radiology being regarded by the profession as a routine procedure. A radiographic request should be the consequence of a clinical decision. Instead, the request has become an accepted procedure from which any departure is almost synonymous with negligence (92). Sherwood (93) argues that requests emanating from clinical decisions will cause the legal system to make different inquiries because the criteria for radiography will have changed. The shift in emphasis will result in testimony based on clinical findings and history-taking rather than radiographic results (92). Similarly, Potchen (33) states that the ordering of x-ray examinations sets the medical as well as the legal standard of care. To alter the latter will require a departure from the automatic request for radiographs. At the National Conference on Referral Criteria for X-Ray Examinations (79), a suggestion was made to develop referral criteria which would assist in protecting physicians from litigation. The criteria would provide definitive standards of medical care and consequently alter the present legal definition of care. The law is concerned with standards of medical care and these are established by the profession (93).

Results of court decisions regarding malpractice suits and pre-trial settlements involving radiographs are inconclusive. In the general area of medical practice, Bonney (94) reports that the common causes of complaint received by the British Defence Societies focus upon failure to admit to the hospital, to order x-ray examinations, and to treat. He notes that failure to order x-ray examinations usually does not result in medical adversities. By example, he refers to trivial fractures and foreign bodies.

A decision by the Supreme Court of Kansas (95) stated that, "It is difficult, if not impossible, to formulate a rule as to when the failure to make use of x-rays in diagnosis may be considered negligence without expert medical testimony on the standard of reasonable care. The answer must depend on the facts and circumstances of each particular case."

Lescoe (96) states that many litigants with fractured skulls have won in court because of a failure to order x-ray examinations. These thoughts were also repeated in the results of

the 1976 Closed Claim Study (97). No instance of suit for excessive radiographs can be found. However, claims and settlements based on missed diagnosis do exist in the legal literature.

In disagreement with Lescoe, others state that suits have not resulted from failure to take skull radiographs (4, 33, 39). These declarations are based on observations and surveys of claims closed by insurance companies. Yet, in a study of 53 cases by Jennett (44), it was shown that 30 of the cases involved skull x-ray examinations in hospitals: 16 failures to obtain skull films, 9 missed fractures, and 5 delayed reports. Jennett does note that part of the problem rests with improper radiographic interpretation or overall inadequate patient management.

Hirsch, Morris, and Moritz (98) contend that the demonstration of a skull fracture has minor medico-legal importance apart from determining that a head injury was sustained. Frequently, this same decision can be made without radiographs. Roberts and Shopfner (28) state, "Medico-legal reasons for skull roentgenography simply to detect fractures are not valid."

Alternative methods have been suggested as a means of diminishing the risk of liability and yet decreasing costs and exposure to needless radiation. For example, St. John (16) and others (16, 38, 43) suggest that radiographs not be performed immediately after head injury but sometime afterwards. By waiting and examining the patient, the actual need for x-ray examinations might be better determined.

Another suggestion is the use of high-yield criteria both to reduce the utilization of skull radiography and to establish an alternative standard of care (98). Hirsch, Morris, and Moritz comment that if two or more approved methods of treatment exist, the physician may adopt the one which in his opinion is more efficacious and appropriate. In such situations, the physician is not liable for injury resulting from an error in judgment.

## REFERENCES


1. Sutherland, J.M. et al. Ancillary investigations in neurological diagnosis. Med J Aust 2:542-6 (1967).

2. Meschan, I. and R.M.F. Farrer-Meschan. Radiographic Positioning and Related Anatomy. W.B. Saunders Co., Philadelphia (1969).

3. Evans, K.T. Radiology now--The radiologist's dilemma. Br J Radiol 50:299-301 (1977).

4. Eyes, B. and A.F. Evans. Post-traumatic skull radiographs: Time for a reappraisal. Lancet 2:85-6 (July 8, 1978).

5. Harwood-Nash, D.C., E.B. Hendrick, and A.R. Hudson. The significance of skull fractures in children. Radiology 101:151-5 (1971).

6. Simpson, J.S. Trauma: The leading childhood killer in Canada and elsewhere. Clin Pediatr 15:313-6 (1976).

7. Weston, P.A.M. Skull x-ray policy. Lancet 2:792 (Oct. 7, 1978).

8. De Smet, A.A., D.G. Fryback, and J.R. Thornbury. A second look at the utility of radiographic skull examination for trauma. AJR 132:95-7 (1979).

9. Phillips, L.A. A Study of the Effect of High Yield Criteria for Emergency Room Skull Radiography. HEW Publication (FDA) 78-8069 (July 1978).

10. Vydareny, K., T.S. Harle, and E.J. Potchen. A diagnostic evaluation of acute head trauma. A paper presented at the Association of University Radiologists and the Society of Chairmen of Academic Radiology Departments, 28th Annual Meeting, Tucson, Arizona, March 25-28, 1980.

11. Ogunmekan, A.O. Routine skull roentgenography in the clinical evaluation of children with febrile convulsions. Br J Radiol 53:815 (1980).

12. Felman, A.H. et al. Skull roentgenography of infants and children with convulsive disorders. Pediatrics 62:835-7 (1978).

13. Blacker, H.M. Closed head injury: A simplified approach. Primary Care 3:231-9 (1976).

14. Mock, H.E. Further studies in skull fractures and brain injuries. Am J Surg 74:502-16 (1947).

15. Diaz, A. and C.E. Parera. Radiography of the Skull and Brain. E.I. du Pont de Nemours and Co., Wilmington (1964).

16. St. John, E.G. The role of the emergency skull roentgenogram in head trauma. AJR 76:315-9 (1956).

17. Bull, J.W.D. and K.J. Zilkha. Rationalizing requests for x-ray films in neurology. Br Med J 4:569-70 (1968).

18. Masters, S.J. Evaluation of head trauma: Efficacy of skull films. AJR 135:539-47 (1980).

19. Felson, B. Letter from the editor. Semin Roentgenol 9(2):87-8 (1974).

20. Hall, F.M. Opinion-Overutilization of radiological examinations. Radiology 120:443-8 (1976).

21. McClenahan, J.L. Editorial: Wasted x-rays. Radiology 96:453-6 (1970).

22. Abrams, H.L. The "overutilization" of x-rays. N Engl J Med 300:1213-6 (1979).

23. Population Exposure to X Rays, U.S., 1964. PHS Publication No. 1519 (1966).

24. Population Exposure to X Rays, U.S., 1970. DHEW Publication (FDA) 73-8047 (November 1973).

25. Estimates of the Population of the United States to March 1, 1980. Current Population Reports, Series P-25, No. 881, p. 25. U.S. Bureau of the Census, Suitland, Md.

26. Bell, R.S. and J.W. Loop. The utility and futility of radiographic skull examinations for trauma. N Engl J Med 284:236-9 (1971).

27. Rosenbaum, H.D., J. Hildner, and W. Hiser. Overutilization of diagnostic radiology by the Department of Medicine of the University of Kentucky Medical Center during August 1972. J Ky Med Assoc 71:233-6 (1973).

28. Roberts, F. and C.E. Shopfner. Plain skull roentgenograms in children with head trauma. AJR 114:230-40 (1972).

29. Jennett, B. Some medico-legal aspects of the management of acute head injury. Br Med J 1:1383-5 (1976).

30. Phillips, L.A. Emergency services utilization of skull radiography. Neurosurgery 4(6): 580-2 (1979).

31. Phillips, L.A. Comparative evaluation of the effect of a high yield criteria list upon skull radiography. JACEP 8:106-9 (1979).

32. Karas, S. Cost containment in emergency medicine. JAMA 243:1356-9 (April 4, 1980).

33. Potchen, E.J. Defensive radiology. In: National Conference on Referral Criteria for X-Ray Examinations, pp. 27-32. HEW Publication (FDA) 79-8083 (April 1979).

34. Lusted, L.B. A Study of the Efficacy of Diagnostic Radiologic Procedures. American College of Radiology, Chicago (1977).

35. Boulis, B.Z.F. and R. Dick. Head injuries in children--Aetiology, symptoms, physical findings and x-ray wastage. Br J Radiol 51:851-4 (1978).

36. Masters, S.J. Evaluation of head trauma: Efficacy of skull films. Am J Neuroradiology 1:329-37 (1980).

37. Stevenson, B.E. Initial management of the acute head injury. Otolaryngol Clin North Am 12:279-91 (1979).

38. Ayella, R.J. Radiology and the massive trauma victim. Am Surg 45:726-8 (1979).

39. Phillips, L.A. Demonstration Project on Emergency Facility Skull Radiography: Final Report of Contract Number HSA-105-74-200. Bureau of Radiological Health, Rockville, Md. (August 7, 1978).

40. Ransohoff, J. and A. Fleischer. Head injuries. JAMA 234:861-4 (1975).

41. Reilly, H.F., E. Sacks, and J.R. Dyke. Penetration of the sagittal sinus by a depressed skull fracture. J Am Med Assoc 202:841-2 (1967).

42. Weiss, M.H. Head trauma and spinal cord injuries: Diagnostic and therapeutic criteria. Crit Care Med 2:311-6 (1974).

43. Hoffmann, C.T. Evaluation and management of linear and depressed skull fractures. Ariz Med 25:179-88 (1968).

44. Jennett, B. Some medicolegal aspects of the management of acute head injury. Br Med J 1:1383-5 (1976).

45. Jennett, B. Skull x-rays after recent head injury. Clin Radiol 31:463-9 (1980).

46. Phillips, L.A. Skull radiography and professional liability. West J Med 131:82-3 (1979).

47. Phillips, L.A. Emergency room skull radiography. In: National Conference on Referral Criteria for X-Ray Examinations, pp. 80-6, HEW Publication (FDA) 79-8083 (April 1979).

48. Obisesan, A.A. and S.P. Bohrer. The uses and abuses of skull x-rays in head injury. Niger Med J 9:65-9 (1979).

49. Jergens, M.E., M.T. Morgan, and C.E. McElroy. Selective use of radiography of the skull and cervical spine. West J Med 127:1-4 (1977).

50. Goldstein, F.P. et al. Varieties of growing skull fractures in childhood. J Neurosurg 33:25-8 (1970).

51. Weston, P.A.M. Skull x ray policy (letter-to-editor). Lancet II:792 (October 7, 1978).

52. Lawaetz, O. Radiographic examination of the cranium in hospitalized patients with head injuries. Ugeskr Laeger 137:551-4 (1975).

53. Lawaetz, O. Radiographic investigation of the cranium in emergency investigation of head injuries in a casualty department. Ugeskr Laeger 137:547-50 (1975).

54. Larsen, K.T. and D.F. Koziol. High yield criteria and emergency department skull radiography: Two community hospitals' experience. JACEP 8:393-5 (1979).

55. Tomsick, T.A., Cordon, I.W., Ehrlich, F.E. and Soler, J.M. Letters-to-the-editor. Ann E Med 9(4):233-4 (1980).

56. Cummins, R.O. and J.P. LoGerfo. Utilization of post-traumatic skull radiography: physician response to a high-yield indication list. A paper submitted for publication in the New England Journal of Medicine, December 1978. Published in part in JAMA 244:673-6 (1980).

57. Freed, H.A. Skull x-ray criteria endorsed by the Food and Drug Administration: Some flaws and proposed modifications. Neurosurgery 7(6):636-8 (1980).

58. Selection Criteria Reduce Unnecessary Skull X Rays. Food and Drug Administration Bulletin, p. 30 (Oct.- Nov. 1978).

58a. Neurosurgical devices and drugs. Neurosurgery 2(3):303-4 (1978).

59. Reynolds, A.F. and Phillips, L.A. Letters-to-the-editor. Neurosurgery 4(2):200 (1979).

60. Koo, A. and R.L. La Roque. Evaluation of head trauma by computed tomography. Radiology 123:345-50 (1977).

61. Zimmerman, R.A. et al. Cranial computed tomography in diagnosis and management of acute head trauma. AJR 131:27-34 (1978).

62. Jamieson, K.G. and J.D. Yelland. Traumatic intracerebral hematoma. Report of 63 surgical cases. J Neurosurg 37:528-32 (1972).

63. Baker, H.L. Computed tomography and neuroradiology: A fortunate primary union. AJR 127:101-10 (1976).

64. Harris, P. Current concepts in the management of brain trauma. J R Coll Surg Edinb 15:268-82 (1970).

65. Naidich, T.P., S. Solomon, and N. Leeds. Computerized tomography in neurological evaluations. JAMA 240:565-8 (1978).

66. Weinstein, M.A., R.J. Alfidi, and P.M. Duchesneau. Guest editorial: Computed tomography vs. skull radiography. AJR 128:873 (1977).

67. Flynn, R.E. The radiological considerations of patients with head trauma. Ariz Med 25:170-4 (1968).

68. Allen, W.E., E.L. Kier, and S.L.G. Rothman. Pitfalls in the evaluation of skull trauma. Radiol Clin North Am 11:479-503 (1973).

69. Grossman, H. et al. Brain tumors in children with normal skull roentgenograms. Am J Roentgenol Ther Nuc Med 112:329-31 (1971).

70. Weeks, L.E. Handling of nonsevere head injuries. JACEP 8:257-60 (1979).

71. Gonad Doses and Genetically Significant Dose from Diagnostic Radiology, U.S., 1964 and 1970. HEW Publication (FDA) 76-8034 (April 1976).

72. Nationwide Evaluation of X-Ray Trends, Tabulations of Representative Sample Data, January 31, 1978 to December 31, 1978. Bureau of Radiological Health, Rockville, Md. (1979).

73. Shleien, B., T.T. Tucker, and D.W. Johnson. The Mean Active Bone Marrow Dose to the Adult Population of the United States from Diagnostic Radiology. HEW Publication (FDA) 77-8013 (January 1977).

74. Rosenstein, M. Handbook of Selected Organ Doses for Projections Common in Diagnostic Radiology. HEW Publication (FDA) 76-8031 (May 1976).

75. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. Report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR Report), pp. 100,120. National Academy of Sciences - National Research Council (November 1972).

76. Handel, S.F., F.O.L. Perpetuo, and C.H. Handel. Subdural hematomas due to ruptured cerebral aneurysms: Angiographic diagnosis and potential pitfall for CT. AJR 130:507-9 (1978).

77. Worttman, G., R.C. Holgate, and P.P. Morgan. Cranial computed tomography: An evaluation of cost effectiveness. Radiology 117:75-7 (1975).

78. Medical Diagnosis: The role of x-rays. Med Malpractice, pp. 34-8 (November 1970).

79. National Conference on Referral Criteria for X-Ray Examinations. HEW Publication (FDA) 79-8083 (April 1979).

80. The medical malpractice threat: A study of defensive medicine. Duke Law J 1971:939-93 (1971).

81. Garg, M.L., W.A. Gliebe, and M.B. Elkhatib. The extent of defensive medicine: Some empirical evidence. Legal Aspects Med Practice 6(2):25-9 (1978).

82. Shore, S. Defensive medicine is good practice. Legal Aspects Med Practice 7:31-5 (1979).

83. Tancredi, L.R. and J.A. Barondess. The problem of defensive medicine. Science 200:879-82 (May 26, 1978).

84. Thomas, W.A. Radiology in malpractice cases. IMJ 153:35-7 (1978).

85. Cole, W.S. The judicious use of diagnostic radiation in the healing arts. Am J Public Health 59:1199-203 (1969).

86. Shanks, S.C. X-ray examination for medico-legal purposes. Clin Biol 37:357-65 (1968).

87. Defensive medicine: How much diagnostic overkill? Med World News, p. 127 (January 12, 1976).

88. Freese, A.S. Managing Your Doctor: How to Get the Best Possible Health Care. Stein and Day Publishers, New York (1975).

89. Medical Malpractice: Report of the Secretary's Commission on Medical Malpractice. DHEW Publication No. (OS) 73-88 (January 16, 1973).

90. Berlin, L. Does the missed radiographic diagnosis constitute malpractice? Radiology 123:523-7 (1977).

91. James, A.E., B.A. Johnson, and D.J. Hall. Informed consent: Some newer aspects and their relation to the specialty of radiology. Radiology 123:809-13 (1977).

92. Pilling, H. A coroner's view of routine radiology. Proc R Soc Med 69(10):760-2 (1976).

93. Sherwood, T. Resources and decisions in clinical radiology. Epidemiol Community Health 33:59-65 (1979).

94. Bonney, G. Medical negligence--The changing scene. Trans Med Soc Lond 89:71-5 (1973).

95. Regan, W.A. ER physicians sued for failure to remove metal fragment. Hosp Prog 59:82 (1978).

96. Lescoe, R. The legal system. In: National Conference on Referral Criteria for X-Ray Examinations, pp. 59-63. HEW Publication (FDA) 79-8083 (April 1979).

97. Westat, Inc. Medical Malpractice Closed Claim Study-1976. Report prepared for National Center for Health Statistics, Office of Statistical Research. Hyattsville, Md. (March 1978).

98. Hirsch, C.S., R.C. Morris, and A.R. Moritz. Handbook of Legal Medicine, 5th ed. The C.V. Mosby Company, St. Louis (1979).

## APPENDIX A

### Summary of Skull Radiography Utility (Efficacy) Studies

| Study | Study period | Sample characteristic | Type of study | No. of skull series requested | No. of fractures detected | Percent yield of fractures | No. of significant fractures | Percent yield of significant fractures* |
|---|---|---|---|---|---|---|---|---|
| St. John | 1951-1955 | Mixed age | Retrospective | 1000 | 150 | 15 | - | - |
| Harwood-Nash, Hendrick and Hudson | Not reported | Children | Retrospective | 4465 | 1187 | 27 | 143 | 3 |
| Eyes and Evans | Not reported | Mixed age | Retrospective | 504 | 9 | 2 | 2 | 0 |
| Bell and Loop | 4/1/69-5/31/70 | Mixed age | Prospective | 1500 | 93 | 6 | 28 | 2 |
| Phillips | 7/1/75-6/30/76 | Mixed age | Retrospective | Univ Hosp: 258<br>Harborview:2275 | Univ Hosp: 18<br>Harborview:114 | Univ Hosp: 7<br>Harborview: 5 | Univ Hosp: 9<br>Harborview:51 | Univ Hosp: 3<br>Harborview: 2 |
| Phillips | 9/1/77-5/31/78 | Mixed age | Prospective | Univ Hosp:<br>w/criteria: 38<br>w/o criteria: 79<br>Harborview:<br>w/criteria: 265<br>w/o criteria:1207 | Univ Hosp:<br>w/criteria: 8<br>w/o criteria:2<br>Harborview:<br>w/criteria: 107<br>w/o criteria:79 | Univ Hosp:<br>w/criteria: 21<br>w/o criteria:3<br>Harborview:<br>w/criteria: 40<br>w/o criteria:7 | Univ Hosp:<br>w/criteria: 6<br>w/o criteria:0<br>Harborview:<br>w/criteria: 73<br>w/o criteria:0 | Univ Hosp:<br>w/criteria: 16<br>w/o criteria:0<br>Harborview:<br>w/criteria: 28<br>w/o criteria:0 |
| Roberts & Shopfner | 1969 | Children | -- | 570 | 49 | 9 | 2 | 0 |
| Hayes & Shopfner | 1965-70 | Children | Retrospective | 234 | 30 abnormalities | - | - | - |
| Jergens, Morgan & McElroy | 10/75-12/75 and 3/76-4/76 | Mixed age | Prospective | 847 | 21 | 2 | 10 | 1 |
| De Smet, Fryback & Thornburg | 11/76-10/77 | Mixed age | Prospective | 594 | 17 | 3 | - | - |
| Masters | 1974 | Mixed age | Retrospective | 1845 | 79 | 4 | 0 | 0 |
| Larsen & Koziol | Alexandria Hospital 1/1/77-10/1/78<br>Mount Vernon Hospital 11/1/76-8/1/78 | Mixed age | Retrospective | - | w/criteria: 39<br>w/o criteria:36 | - | 5 | - |
| Cummings & LoGerfo | 12/76-3/77 (baseline)<br>12/77-3/78<br>12/78-3/79 | Mixed age | Prospective | 962 | 65 | 7 | - | - |

*Calculated by dividing the number of significant fractures by the number of skull series requested.

## APPENDIX B

### Bell and Loop High-Yield Criteria List
### Harborview Medical Center and University Hospital
### 1970

History

1. Greater than 5 minutes of unconsciousness
2. Greater than 5 minutes of retrograde amnesia
3. Vomiting
4. Nonvisual focal symptoms
5. Accident at work or gunshot wound

Physical examination

6. Palpable bony malalignment
7. Discharge from ear
8. Discharge from nose
9. Ear-drum discoloration
10. Bilateral black eyes

Neurologic examination

11. Stupor, semiconsciousness or coma
12. Breathing irregular or apneic
13. Babinski reflex present
14. Other reflex abnormality
15. Focal weakness
16. Sensory abnormality
17. Anisocoria
18. Other cranial-nerve abnormality

Physical evaluation

19. Injury considered "severe"
20. Odds for fracture "50:50" or "9:1 certain"
21. Examination because "fracture seriously suspected"

## APPENDIX C

### High-Yield Criteria List
### The University Hospital Utilization Review Committee
### September 1, 1973 to August 30, 1974

Historical Criteria

1. Unconscious more than five minutes
2. Retrograde amnesia more than five minutes
3. Vomiting
4. Gunshot wound or accident at work
5. Nonvisual focal symptoms

General Physical Exam Criteria

6. Palpable bony malalignment
7. Discharge from ear
8. Discharge from nose
9. Ear-drum discoloration
10. Bilateral black eyes

Neurologic Examination Criteria

11. Stupor, semiconsciousness or coma
12. Irregular breathing or apneic
13. Babinski reflex present
14. Other reflex abnormality
15. Focal weakness
16. Sensory abnormality
17. Anisocoria
18. Other cranial-nerve abnormality

Other Criteria

19. (Please Specify)

## APPENDIX D

**Modified High-Yield Criteria List**
**University of Washington Hospital**
**April 1, 1975 - March 31, 1976**

The Trauma Skull Film Policy for the University Hospital now states that any physician can request radiographic examination of the skull if any of the following are present:

Historical Criteria — Please check

1. Unconscious_____minutes (please estimate)
2. Retrograde amnesia_____minutes (please estimate)
3. Skull penetration suspected
4. Focal symptoms
5. Patient on anticoagulants

General Physical Exam Criteria

6. Palpable bony malalignment or bulging
7. Discharge from ear
8. Discharge from nose
9. Ear drum discoloration
10. Bilateral black eye (suspected base fracture)

Neurological Examination Criteria

11. Stupor or coma
12. Irregular breathing
13. Focal neurological sign, describe_____

If you have a patient whom you believe needs skull films and does fit the above criteria, the neurology resident or the Emergency Department supervisor must concur and this concurrence must be noted on the radiographic request.

## APPENDIX E

### Second Modified High-Yield Criteria List
### University of Washington Hospital
### August 1976

All patients presenting to the University Hospital Emergency Medicine Service with complaints or symptoms referable to the cranium or its contents, or with a history of probable trauma to the same, should receive a careful and complete clinical evaluation.

If any of the following criteria are present, a skull radiogram should be requested. This request must include a detailed description of the criteria that prompt the need for the radiograph. If none of these criteria is present and you believe that a skull radiograph should be performed, you must seek consultation with the neurosurgery resident, neurology resident or the full-time Emergency Medicine Service faculty physician.

Historical Criteria

1. An established history of unconsciousness
2. Gunshot wound or skull penetration
3. Previous craniotomy with shunting tube in place.

Physical Exam Criteria

4. Skull depression palpable or identified by probe in scalp laceration
5. Discharge from the ear
6. CSF discharge from nose
7. Blood in middle ear cavity
8. Battle's sign
9. Racoon's eyes
10. Presence of coma or stupor (not related to alcoholic ingestion)
11. Focal neurological signs.

Concurrent monitoring of skull radiography will be continued by the Utilization Review Committee. A monthly summary will be prepared for all concerned physicians.

## APPENDIX F

### Masters High-Yield Criteria List
### 1979

History

1. Unconscious: 10 minutes or longer
2. Confusion
3. Penetrating wound
4. Seizure: acute or acute + chronic

Neurologic exam

5. Altered consciousness including confusion, lethargy, irritability, responsiveness to pain, miscellaneous and unspecified
6. Amnesia: retrograde + peri-factual
7. Irregular breathing
8. Babinski
9. Abnormal Deep Tendon Reflex: increased, decreased or absent
10. Focal weakness (hemi-quadri-para-paresis/plegia, extensor-posturing, et al.
11. Miscellaneous sensory abnormality
12. Visual dysfunction: fixed and dilated, aniscoria + fixed, other visual abnormalities
13. Miscellaneous abnormal cranial nerve
14. Abnormal named reflex or sign
15. Miscellaneous (unsteady gait, ataxia, cerebellar signs, et al.)

## APPENDIX G

### Summary of Cases in University of Washington Investigation

The first case involved a male patient who was thrown to the ground by a car starting from a parked position. The patient presented in the emergency room (ER) confused, alcohol on his breath, and unable to give a history after a lucid interval of several minutes. The clinical examination revealed stuporousness, intermittent agitation, incontinence, lip laceration, a broken tooth, and an occipital scalp laceration. After a 4-hour observation period, the patient was awake, coherent, could answer questions appropriately, and moved about satisfactorily. He was released but brought back to the ER 5 hours later. He was unconscious, had been hitting himself and acting strangely. He was found to be deeply comotose, with unequal fixed pupils, no corneal or gag reflexes, decorticate on the left and decerebrate on the right, with Babinski signs. A total of 50 cc of freshly clotted blood was removed from the frontal case. However, the patient died later and cause of death was listed as skull fracture, cerebral contusions, and subdural hematoma. Had skull films been taken during the first period in ER the fracture would have been discovered and further CNS trauma workup would have revealed the subdural hematoma.

An 85-year old male found lying in front of a tavern was brought into the ER in an obtunded state, vital signs were initially normal, except for mild hypertension and mild head injuries, e.g., abrasions and a hematoma over the right lateral, posterior scalp. The neurological examination showed no lateralizing findings or significant abnormality other than the level of unconsciousness. While awaiting laboratory results, the patient became more deeply unconscious, developed fixed, unequal pupils, and depressed respirations. A closer examination, including shaving the head, and skull radiographs revealed a right temporo-parietal fracture. A right epidural hematoma was evacuated; however, the patient died two days later. The investigators felt that either quicker movement to obtain skull films or closer clinical observation could have resulted in an earlier evacuation of the epidural hematoma.

The third case concerned a 79-year old patient who was run over by a pickup truck. The patient had severe body injuries including multiple pelvic fractures, a flail chest, and a skull fracture. The latter was not discovered until the second day in the hospital at which time skull radiographs revealed a basilar fracture. The patient died 20 days later of pulmonary and metabolic complications. It was the opinion of the reviewers that in this case delay in obtaining skull films represented only an incidental problem and probably did not significantly impair the patient's therapy.

## APPENDIX H

### Analysis of the Potential Radiation Risk to the U.S. Population from the Use of Skull Radiographs

This analysis was performed using worst-case assumptions to determine the hypothetical lifetime cancer risk to patients that could result from the use of skull radiographs (PA, AP, and lateral views) using the estimates of involved population derived from the 1970 PHS X-Ray Exposure Study.

Red bone marrow and the thyroid are assumed to be at some risk from skull radiographs. The risk to other organs such as the eye and pituitary gland is assumed to be negligible. The following table shows the information necessary to calculate the incidence of thyroid cancer and leukemia.

Calculation of Risk Estimate

| Skull Projections | Frequency [a] | Mean Exposure at Skin Entrance [a] | Mean Active Bone Marrow Dose in mrad [b] | Thyroid Dose in mrad [b] |
|---|---|---|---|---|
| AP | 4,715,160 | 419 mR | 4 | 115 |
| Lateral | 7,101,260 | 246 mR | 7 | 29 |
| PA | 4,239,710 | 391 mR | 10 | 8 |

[a] Unpublished data derived from x-ray exposure study for 1970. (See Population Exposure to X Rays - U.S. 1970, DHEW Publication FDA 73-8047 for study methodology. The projections shown account for about 94 percent of all examinations. The projection frequency includes both sexes and all ages.

[b] Calculations based on Handbook of Selected Organ Doses for Projections Common in Diagnostic Radiology (FDA 76-8031). It was assumed that the half-value layer (HVL) was 2.5 mm Al.

Leukemia Risk for All Types of Skull Examinations

Risk = 25 cases per million person rads*

Total leukemia cases = (No. persons exposed) x (rads/exposure) x (cases/person-rads)

AP projection (4,715,160) x (0.004 rads/exp.) x (25 cases/$10^6$ person rads) = 0.47 cases
Lateral projection (7,101,260) x (0.007 rads/exp.) x (25 cases/$10^6$ person rads) = 1.24 cases
PA projection (4,239,710) x (0.011 rads/exp.) x (25 cases/$10^6$ person rads) = 1.17 cases

Total leukemia cases from all projections = 2.88 cases

Thus, after the latent period, one would expect to see approximately 3 additional cases of leukemia in the population exposed to skull x rays during 1970. By way of comparison, the American Cancer Society has estimated that 22,200 new cases of leukemia occurred in the U.S. population in 1980.+

Thyroid Cancer Risk for All Types of Skull Examinations

Risk = 100 cases per million person rads*

Total thyroid cases = (No. persons exposed) x (rads/exposure) x (cases/person rads)

AP projection (4,715,160) x (0.115 rads/exp.) x (100 cases/$10^6$ person rads) = 54.2 cases
Lateral projection (7,101,260) x (0.029 rads/exp.) x (100 cases/$10^6$ person rads) = 20.6 cases
PA projection (4,239,710) x (0.008 rads/exp.) x (100 cases/$10^6$ person rads) = 3.39 cases

Total cases of thyroid cancer from all projections = 78.2 cases

Again, after the latent period, one would expect to see approximately 78 additional cases of thyroid cancer in the population exposed to skull x rays during 1970. The American Cancer Society has estimated that 9,100 new cases of thyroid cancer occurred in the U.S. population in 1980.+

*Sources and Effects of Ionizing Radiation. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 1977 Report to the General Assembly.

+Cancer Facts and Figures, 1980. Published by the American Cancer Society, 777 Third Ave., New York, NY 10017.

*U.S. GOVERNMENT PRINTING OFFICE : 1981 0-341-177/202

FDA 81-8027 Directory of Personnel Responsible for Radiological Health Programs (supersedes FDA 80-8027, March 1980).

FDA 81-8033 Bureau of Radiological Health Publications Index (supersedes FDA 79-8033) (PB 81-156192, $18.50).

FDA 81-8034 Report of State and Local Radiological Health Programs, Fiscal Year 1979 (PB 81-167678, $6.50).

FDA 81-8042 CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1979 (PB 81-184566, $15.50).

FDA 81-8070 Bureau of Radiological Health Publications Subject Index (supersedes FDA 80-8070, May 1980) (PB 81-149478, $5.00).

FDA 81-8136 Optical Radiation Emissions from Selected Sources: Part I - Quartz Halogen and Fluorescent Lamps (GPO 017-015-00177-6, $6.50) (PB 81-139693, mf only).

FDA 81-8139 Quality Assurance in Diagnostic Ultrasound - A Manual for the Clinical User (GPO 017-015-00179-2, $4.00) (PB 81-139727, mf only).

FDA 81-8141 Quality Assurance in Diagnostic Radiology and Nuclear Medicine - The Obvious Decision (PB 81-164477, $14.00).

FDA 81-8142 Use of Photographic Film to Estimate Exposure Near the Three Mile Island Nuclear Power Station (PB 81-183402, $6.50).

FDA 81-8143 Procedures for Evaluating Nonperturbing Temperature Probes in Microwave Fields (GPO 017-015-00189-0, $2.75) (PB 81-205882, mf only).

FDA 81-8144 Assembler's Guide to Diagnostic X-Ray Equipment.

FDA 81-8146 Radiographic Film Processing Quality Assurance: A Self-Teaching Workbook (GPO 017-015-00180-6. $4.00) (PB 81-163974, mf only).

FDA 81-8147 Quality Assurance in Diagnostic Radiology: A Guide for State Program Implementation (PB 81-175747, $9.50).

FDA 81-8150 The Correlated Lecture Laboratory Series in Diagnostic Radiological Physics (GPO 017-015-00184-9, $4.50) PB 81-183444, mf only).

FDA 81-8151 A Feasibility Study of the Biological Effects of Fallout on People in Utah, Nevada, and Arizona (PB 81-187692, $5.00).

FDA 81-8152 Annual Report of the Division of Biological Effects, Bureau of Radiological Health - Fiscal Year 1979 (PB 81-187155, $11.00).

FDA 81-8153 An Evaluation of Radiation Emission from Video Display Terminals (GPO 017-015-00187-3, $4.25) (PB 81-198483, mf only).

FDA 81-8155 A Practitioner's Guide to the Diagnostic X-Ray Equipment Standard (GPO 017-015-00185-7, $1.25).

FDA 81-8156 Symposium on Biological Effects and Measurement of Light Sources (GPO 017-015-00191-1, $6.50) (PB 81-214223, mf only).

FDA 81-8157 An Intercomparison of Nuclear Medicine, Ultrasonography, and Computed Tomography in the Diagnosis of Liver Disease: A Retrospective Study (PB 81-199044, $6.50).

FDA 81-8158 Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid-Blocking with Potassium Iodide (GPO 017-015-00188-1, $2.25) (PB 81-205361, mf only).

FDA 81-8161 BRH Routine Compliance Testing for Diagnostic X-Ray Systems (PB 81-201501, $15.50).

FDA 81-8162 Handbook of Computed Tomography -X-Ray Spectra (PB 81-295890, $11.00).

FDA 81-8163 Airborne Ultrasound: Measurement and Possible Adverse Effects (GPO 017-015-00193-8, $2.00).

FDA 81-8164 Calculation Programs for Routine Compliance Testing of Diagnostic X-Ray Systems (PB 81-200503, $8.00).

FDA 81-8166 Third International Radiopharmaceutical Dosimetry Symposium (October 1980 (GPO 017-015-00194-6, $11.00).

FDA 81-8171 Self-Assessment and Competency Assurance Education in Diagnostic Radiologic Technology: Final Report (September 30, 1977 to April 30, 1980).

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